



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1027]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions in FDA's infant formula recall regulations.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Infant Formula Recall Regulations--21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280
(OMB Control Number 0910-0188)--Extension

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the FD&C Act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the FD&C Act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations in part 107 (21 CFR part 107) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone

within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait FDA's written concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination, nutritional inadequacy, or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

FDA estimates the annual burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
107.230; Elements of infant formula recall	2	1	2	4,450	8,900
107.240; Notification requirements	2	1	2	1,482	2,964
107.250; Termination of infant formula recall	2	1	2	120	240
107.260; Revision of an infant formula recall ²	1	1	1	625	625
Total					12,729

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting and third-party disclosure burden estimates are based on FDA's records, which show that there are 5 manufacturers of infant formula and that there have been, on average, 2 infant formula recalls per year for the past 3 years. Based on this information, FDA estimates that there will be, on average, approximately 2 infant formula recalls per year over the next 3 years.

Thus, FDA estimates that 2 respondents will conduct recalls annually pursuant to §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because FDA seldom uses this section; therefore, FDA estimates that there will be 1 or fewer respondents annually for § 107.260. The estimated number of hours per response is an average based on FDA's experience and information from firms that have conducted recalls. FDA estimates that 2 respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 4,450 hours to comply with the requirements of that section, for a total of 8,900 hours. FDA estimates that 2 respondents will conduct infant formula recalls under § 107.240 and that it will take a respondent 1,482 hours to comply with the requirements of that section, for a total of 2,964 hours. FDA estimates that 2 respondents will submit recommendations for termination of infant formula recalls under § 107.250 and that it will take a respondent 120 hours to comply with the requirements of that section, for a total of 240 hours. Finally, FDA estimates that one respondent will need to carry out additional effectiveness checks and issue additional notifications, for a total of 625 hours.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the

recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

Table 2.--Estimated Annual Third-Party Disclosure Burden¹

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
107.230; Elements of infant formula recall	2	1	2	50	100
107.260; Revision of an infant formula recall	1	1	1	25	25
Total					125

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 reports FDA's third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on FDA's experience. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct-account (customer) about the recall, and if the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post a notice of the recall at the point of purchase. FDA estimates that 2 respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. FDA estimates that 1 respondent will issue additional notifications under § 107.260 and that it will take a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours.

Dated: August 1, 2014.

Peter Lurie.

Associate Commissioner for Policy and Planning.

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